Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

British Association of Dermatologists guidelines for biologic therapy for psoriasis 2017.

Bibliographic Source(s)

Smith CH, Jabbar-Lopez ZK, Yiu ZZ, Bale T, Burden AD, Coates LC, Cruickshank M, Hadoke T, MacMahon E, Murphy R, Nelson-Piercy C, Owen CM, Parslew R, Peleva E, Pottinger E, Samarasekera EJ, Stoddart J, Strudwicke C, Venning VA, Warren RB, Exton LS, Mohd Mustapa MF. British Association of Dermatologists guidelines for biologic therapy for psoriasis 2017. Br J Dermatol. 2017 Sep;177(3):628-36. [17 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Smith CH, Anstey AV, Barker JN, Burden AD, Chalmers RJ, Chandler DA, Finlay AY, Griffiths CE, Jackson K, McHugh NJ, McKenna KE, Reynolds NJ, Ormerod AD. British Association of Dermatologists' guidelines for biologic interventions for psoriasis 2009. Br J Dermatol. 2009 Nov;161(5):987-1019. [226 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report Clinical Practice Guidelines We Can Trust.

= Poor = Fair = Good = Very Good = Excellent

Assessment	Standard of Trustworthiness
YES	Disclosure of Guideline Funding Source
	Disclosure and Management of Financial Conflict of Interests

	Guideline Development Group Composition
YES	Multidisciplinary Group
YES	Methodologist Involvement
▮▮▮▮▯	Patient and Public Perspectives
	Use of a Systematic Review of Evidence
▮▮▮▮▮	Search Strategy
▮▮▮▮▮	Study Selection
▮▮▮▮▮	Synthesis of Evidence
	Evidence Foundations for and Rating Strength of Recommendations
▮▮▮▮▮	Grading the Quality or Strength of Evidence
▮▮▮▮▮	Benefits and Harms of Recommendations
▮▮▮▮▮	Evidence Summary Supporting Recommendations
▮▮▮▮▮	Rating the Strength of Recommendations
▮▮▮▮▮	Specific and Unambiguous Articulation of Recommendations
▮▮▮▮▮	External Review
▮▮▮▮▮	Updating

Recommendations

Major Recommendations

Note from the National Guideline Clearinghouse (NGC): See the "Availability of Companion Documents" field for the full version of this guidance and related appendices.

Definitions for the strength of recommendations (Strong For, Weak For, No Recommendation, Strong Against) are provided at the end of the "Major Recommendations" field.

Summary of Recommendations

Using Biologic Therapy

Recommendation 1. Initiation and supervision of biologic therapy for people with psoriasis should be undertaken by specialist physicians experienced in the diagnosis and treatment of psoriasis. Routine monitoring may be delegated to other healthcare professionals, e.g., clinical nurse specialists. Manage psoriatic arthritis and/or multimorbidity in consultation with the relevant healthcare professionals. (Strong recommendation *for* the use of an intervention)

Recommendation 2. Agree and formalize arrangements for drug administration, monitoring and follow-up

between health carers and the person receiving treatment. (Strong recommendation *for* the use of an intervention)

Recommendation 3. Offer people with psoriasis who are starting biologic therapy the opportunity to participate in long-term safety registries (British Association of Dermatologists Biologic Interventions Register [BADBIR] in the United Kingdom [U.K.] and Republic of Ireland; http://www.badbir.org). (Strong recommendation *for* the use of an intervention)

Criteria for Biologic Therapy

Recommendation 4. Offer biologic therapy to people with psoriasis requiring systemic therapy if methotrexate and ciclosporin have failed, are not tolerated or are contraindicated (see the National Institute for Health and Care Excellence [NICE] guideline on Psoriasis: assessment and management) and the psoriasis has a large impact on physical, psychological or social functioning (e.g., Dermatology Life Quality Index [DLQI] or Children's DLQI >10 or clinically relevant depressive or anxiety symptoms) and one or more of the following disease severity criteria apply:

- The psoriasis is extensive (defined as body surface area [BSA] >10% or Psoriasis Area and Severity Index [PASI] ≥10)
- The psoriasis is severe at localized sites and associated with significant functional impairment and/or high levels of distress (e.g., nail disease or involvement of high-impact and difficult-to-treat sites such as the face, scalp, palms, soles, flexures and genitals).

(Strong recommendation *for* the use of an intervention)

Recommendation 5. Consider biologic therapy earlier in the treatment pathway (e.g., if methotrexate has failed, is not tolerated or is contraindicated) in people with psoriasis who fulfil the disease severity criteria and who also have active psoriatic arthritis (see the NICE interactive flowchart) or who have psoriasis that is persistent, i.e., that relapses rapidly (defined as >50% baseline disease severity within 3 months of completion of any treatment) off a therapy that cannot be continued in the long-term (e.g., narrowband ultraviolet B). (Weak recommendation *for* the use of an intervention)

Prescribing Biologic Therapy

Recommendation 6. Be aware of the benefits of, contraindications to and adverse effects associated with biologic therapies and reference the drug-specific summary of product characteristics (SPCs) (www.medicines.org.uk/emc). (Strong recommendation *for* the use of an intervention)

Recommendation 7. Provide high-quality, evidence-based information to people being prescribed biologic therapies. Explain the risks and benefits to people undergoing this treatment (and their families or carers where appropriate), using absolute risks and natural frequencies when possible (see the decision aid in the Implementation Toolkit [see the "Availability of Companion Documents" field]). Allow them adequate time to consider the information. (Strong recommendation *for* the use of an intervention)

Recommendation 8. Support and advice should be offered to people with psoriasis (and their families or carers where appropriate) by healthcare professionals who are trained and competent in the use of biologic therapies. (Strong recommendation *for* the use of an intervention)

Reviewing Biologic Therapy

Recommendation 9. Assess initial response to biologic therapy in people with psoriasis at time points appropriate for the drug in question, and then on a regular basis during therapy (e.g., every 6 months). (Strong recommendation *for* the use of an intervention)

Recommendation 10. Review response to biologic therapy by taking into account:

- Psoriasis disease severity compared with baseline (e.g., PASI baseline to end point score) (see the

BAD Healthcare professionals forms)

The agreed treatment goal
Control of psoriatic arthritis disease activity and/or inflammatory bowel disease (in consultation with a rheumatologist and/or gastroenterologist)
The impact of psoriasis on the person's physical, psychological and social functioning
The benefits vs. the risks of continued treatment
The views of the person undergoing treatment (and their family or carers, where appropriate)
Adherence to the treatment.

(Strong recommendation *for* the use of an intervention)

Recommendation 11. Assess whether the minimal response criteria have been met, as defined by:

≥50% reduction in baseline disease severity (e.g., PASI 50 response, or percentage BSA where PASI is not applicable) and
Clinically relevant improvement in physical, psychological or social functioning (e.g., ≥4-point improvement in DLQI or resolution of low mood).

(Weak recommendation *for* the use of an intervention)

Recommendation 12. Consider changing to an alternative therapy, including another biologic therapy, if any of the following applies:

The psoriasis does not achieve the minimum response criteria (primary failure – see Recommendation 11)
The psoriasis initially responds but subsequently loses this response (secondary failure)
The current biologic therapy cannot be tolerated or becomes contraindicated.

(Weak recommendation *for* the use of an intervention)

Choice of Biologic Therapy: General Considerations

Recommendation 13. Take into account both psoriasis and psoriatic arthritis before initiating or making changes to biologic therapy, and

Manage treatment in consultation with a rheumatologist or paediatric rheumatologist
Be aware that the presence of and phenotype of psoriatic arthritis (e.g., peripheral vs. axial disease) may influence access to, choice of and dose of biologic therapy.

(Strong recommendation *for* the use of an intervention)

Recommendation 14. Tailor the choice of agent to the needs of the person and take into account the following factors (see the decision aid in the Implementation Toolkit [see the "Availability of Companion Documents" field]): (Strong recommendation *for* the use of an intervention)

Psoriasis Factors

The goal of therapy (e.g., Physician's Global Assessment [PGA] of clear or nearly clear)
Disease phenotype and pattern of activity
Disease severity and impact
The presence of psoriatic arthritis (in consultation with an adult or paediatric rheumatologist)
Outcomes of previous treatments for psoriasis.

Other Factors

Person's age
Past or current comorbid conditions (e.g., inflammatory bowel disease, cardiovascular disease)
Conception plans
Body weight
The person's views and any stated preference on administration route or frequency

Adherence.

Recommendation 15. Be aware that the recommended first-line choice of biologic therapy will not be appropriate for every individual; use the decision aid and reference to Recommendation 14 to inform the choice of alternative licensed biologic therapies. (Strong recommendation *for* the use of an intervention)

Choice of Biologic Therapy in Adults: First Line

Recommendation 16. Offer ustekinumab as a first-line biologic agent to adults with psoriasis who fulfil the criteria for biologic therapy (see also Recommendations 4 and 5). (Strong recommendation *for* the use of an intervention)

Recommendation 17. Offer adalimumab as a first-line biologic agent to adults with psoriasis particularly when psoriatic arthropathy is a consideration. (Strong recommendation *for* the use of an intervention)

Recommendation 18. Consider secukinumab as a first-line biologic agent in adults with psoriasis, with or without psoriatic arthritis. (Weak recommendation *for* the use of an intervention)

Choice of Biologic Therapy in Adults: Second Line

Recommendation 19. Offer any of the currently licensed biologic therapies when psoriasis has not responded to a first biologic therapy. Use the decision aid (see the "Availability of Companion Documents" field) and take into account all factors detailed in Recommendation 14 to select the most appropriate agent. (Strong recommendation *for* the use of an intervention)

Other Considerations

Recommendation 20. Reserve infliximab for use in people with very severe disease or where other available biologic agents have failed or cannot be used (see the NICE guideline on Psoriasis: assessment and management). (Strong recommendation *for* the use of an intervention)

What to Do When a Second or Subsequent Biologic Therapy Fails in Adults

Recommendation 21. When a person's psoriasis responds inadequately to a second or subsequent biologic agent seek advice from a clinician with expertise in biologic therapy and consider any of the following strategies:

- Reiterate advice about modifiable factors contributing to poor response (e.g., obesity and poor adherence)
- Optimize adjunctive therapy (e.g., switch from oral to subcutaneous methotrexate)
- Switch to an alternative biologic agent
- Consider nonbiologic therapy approaches (e.g., inpatient topical therapy, phototherapy or standard systemic therapy).

(Weak recommendation *for* the use of an intervention)

When to Consider Dose Escalation

Recommendation 22. Consider escalating the dose of biologic therapy in adults where this is feasible and funded (see table below) and when an inadequate primary response may be due to insufficient drug dosing (e.g., in people who are obese or whose psoriasis relapses during the treatment cycle). Take into account that this may be associated with an increased risk of infection, and, depending on the drug (e.g., ustekinumab and infliximab), off-license. (Weak recommendation *for* the use of an intervention)

Biologic Agent	Suggested Dose-escalation Strategy
Ustekinumab 45 mg every 12 weeks (<100 kg)	Ustekinumab 90 mg every 12 weeks (<100 kg)
Ustekinumab 90 mg every 12 weeks (>100 kg)	Ustekinumab 90 mg every 8 weeks (>100 kg)
Adalimumab 40 mg every other week	Adalimumab 40 mg weekly
Etanercept 50 mg once weekly	Etanercept 50 mg twice weekly

Biologic Agent	Suggested Dose-escalation Strategy
Infliximab 5 mg kg^{-1} every 8 weeks	Infliximab 5 mg kg^{-1} every 6 weeks

Choice of Biologic Therapy in Children and Young People

Recommendation 23. Offer adalimumab (age ≥4 years), etanercept (≥6 years) or ustekinumab (≥12 years) to children and young people who fulfil the criteria for biologic therapy (see also Recommendations 4 and 5). (Strong recommendation *for* the use of an intervention)

Recommendation 24. When a child's or young person's psoriasis responds inadequately to a first or subsequent biologic agent seek advice from a clinician with expertise in biologic therapy and consider any of the following strategies:

- Reiterate advice about modifiable factors contributing to poor response (e.g., obesity and poor adherence)
- Optimize adjunctive therapy (e.g., switch from oral to subcutaneous methotrexate)
- Switch to an alternative biologic agent
- Consider nonbiologic therapeutic approaches (e.g., inpatient topical therapy or standard systemic therapy).

(Weak recommendation *for* the use of an intervention)

Transitioning to or Between Biologic Therapies

Recommendation 25. When choosing the transitioning strategy from one drug therapy to another and whether a therapy washout (or no washout) should be used, take into consideration

- The pharmacology of the drugs that are being started and stopped (see the summary of licensed indications and posology for biologic therapy in the Implementation Toolkit [see the "Availability of Companion Documents" field])
- The person's clinical circumstances
- The person's views on the risks and benefits of transitioning option(s).

(Strong recommendation *for* the use of an intervention)

Recommendation 26. Consider the following strategies when transitioning from standard systemic to biologic therapy:

- In stable disease, aim to allow 1 month to elapse between the last dose of any current standard systemic immunosuppressant psoriasis therapy (except methotrexate) and the planned date of biologic initiation
- Start a biologic therapy with no drug washout period in people taking methotrexate, or in people on other therapies where this would lead to unstable disease
- When standard, systemic immunosuppressant therapy cannot be stopped (e.g., in people for whom a disease flare would be severe or hazardous), rationalize use of therapy and stop as soon as possible (e.g., when a minimum response has been achieved).

(Weak recommendation *for* the use of an intervention)

Recommendation 27. When transitioning to a new biologic therapy (from a previous biologic therapy) consider using a 1-month washout period, or the length of the treatment cycle (whichever is longer), between the last dose of the current biologic therapy and the planned date of biologic initiation. (Weak recommendation *for* the use of an intervention)

Conception and Pregnancy

Recommendation 28. Provide information about the possible effects of biologic therapy during conception and pregnancy, including

- The importance of controlling severe or unstable psoriasis to maintain maternal health

That most pregnancies reported in women taking biologic therapy at conception and during pregnancy have successful outcomes
That evidence about the effect of biologic therapy on conception and pregnancy mostly relates to tumour necrosis factor (TNF) antagonists in women with rheumatological and inflammatory bowel disease; this evidence indicates a potential risk associated with exposure to TNF antagonists but is of low quality, and may relate to other factors (e.g., other cotherapies or the underlying disease).
That the risk of fetal abnormalities in women with psoriasis who conceive on biologic therapy has not been adequately studied and therefore cannot be quantified
That maternal immunoglobulin G (IgG), and therefore biologic drugs currently licensed for psoriasis, is actively transferred to the developing fetus during the second and third trimester and that the impact of this on fetal and neonatal development and risk of infection have not been adequately studied
That live vaccines must be avoided in infants born to mothers taking biologic therapy beyond 16 weeks' gestation
Relevant patient information resources (see the Best Use of Medicines in Pregnancy [BUMPS] Web site).

(Strong recommendation *for* the use of an intervention)

Recommendation 29. Advise women of childbearing potential who are starting biologic therapy for psoriasis to use effective contraception and discuss conception plans with the consultant supervising their care (see Recommendation 30). There are no known interactions between biologic therapies and contraceptive methods (see drug-specific SPCs). (Strong recommendation *for* the use of an intervention)

Recommendation 30. Discuss the risks and benefits of continuing vs. stopping biologic therapy with women who are of childbearing potential or who become pregnant. Offer advice on a case-by-case basis by taking into account the woman's views and

The course of psoriasis disease and the fetal outcome during any prior pregnancies
The risk of severe or unstable psoriasis if the biologic therapy were stopped
The physical, psychological and social functioning if the biologic therapy were stopped
The options for alternative, nonbiologic treatment strategies.

(Strong recommendation *for* the use of an intervention)

Recommendation 31. Assess whether biologic therapy for psoriasis can be stopped in women who become pregnant. Ensure consultation and information sharing across specialities including with an obstetrician who has expertise in caring for pregnant women with medical problems. Collect pregnancy outcome data for safety registries, e.g., BADBIR in the U.K. and Republic of Ireland. (Strong recommendation *for* the use of an intervention)

Recommendation 32. Advise mothers who have received biologic therapy for psoriasis beyond 16 weeks' gestation that their infants should not receive any live vaccinations until they have reached 6 months of age (e.g., rotavirus and BCG). (Strong recommendation *for* the use of an intervention)

Biologic Therapy and Cancer Risk

Recommendation 33. Assess people with psoriasis prior to, and during treatment with, biologic therapy with respect to

Their past or current history of cancer (see Recommendation 35) and/or
Any future risk of cancer.

(Strong recommendation *for* the use of an intervention)

Recommendation 34. Provide information to people with psoriasis about the importance of participating in national cancer screening programmes. (Strong recommendation *for* the use of an intervention)

Recommendation 35. Exercise caution and discuss with the relevant cancer specialist when prescribing

biologics in people with psoriasis and

- A history of cancer, particularly if this has been diagnosed and treated <5 years previously and/or Where the baseline risk of skin cancer is increased (e.g., previously treated nonmelanoma skin cancer).

(Strong recommendation *for* the use of an intervention)

Biologic Therapy and Infections

Recommendation 36. Assess people with psoriasis prior to, and during treatment with, biologic therapy with respect to

- Risk factors for infection (e.g., comorbidities, cotherapy, lifestyle and travel)
- Known infections (past or current)
- Signs or symptoms suggestive of infection.

(Strong recommendation *for* the use of an intervention)

Biologic Therapy and Chronic Viral Infections: Hepatitis B, Hepatitis C and HIV

Recommendation 37. Test for infection with hepatitis B (surface antigen and core antibody), hepatitis C (IgG) and HIV (human immunodeficiency virus [HIV]-1 and HIV-2 antibodies and HIV-1 antigen) in people starting biologic therapy. (Strong recommendation *for* the use of an intervention)

Recommendation 38. Consider ongoing screening (e.g., annually) for hepatitis B, hepatitis C and HIV, particularly in people who belong to a group at increased risk of infection (refer to Section 4 in the Implementation Toolkit [see the "Availability of Companion Documents" field]) (see the British HIV Association [BHIVA] guideline on Routine investigation and monitoring of adult HIV-1-positive individuals). (Weak recommendation *for* the use of an intervention)

Recommendation 39. Retest for viral hepatitis in any person who develops unexplained transaminitis (raised alanine aminotransferase and/or aspartate aminotransferase); retest for HIV infection in any person who has symptoms of HIV seroconversion. (Strong recommendation *for* the use of an intervention)

Recommendation 40. Consult a hepatitis specialist when treating all people with biologic therapy who have hepatitis B or C infection, whether newly diagnosed or previously known. (Strong recommendation *for* the use of an intervention)

Recommendation 41. Provide treatment options to people with psoriasis who are HIV seropositive on a case-by-case basis; be aware that severe psoriasis can occur in people with uncontrolled HIV infection. Involve relevant specialists and ensure HIV viral load is suppressed on antiretroviral therapy before considering biologic therapy. (Strong recommendation *for* the use of an intervention)

Recommendation 42. Test for varicella zoster (VZ) virus antibody in people with a negative or uncertain history for chickenpox; consider varicella vaccination in those who are not varicella immune and seek expert advice. Be aware of the indications for using VZ immunoglobulin in VZ-susceptible individuals (refer to the Public Health England Guidance for issuing varicella-zoster immunoglobulin [VZIG]). (Good Practice Point [GPP])

Use of Biologic Therapy and TB

Recommendation 43. Screen for latent TB with an interferon-γ release assay. Arrange a plain chest radiograph to rule out abnormalities at baseline including granulomas indicative of prior infection and other confounding lung diseases. If positive, assess for active TB and/or management of latent TB in consultation with a TB specialist (see the NICE guideline on Tuberculosis). (Strong recommendation *for* the use of an intervention)

Recommendation 44. In people who require treatment for latent TB (3 months of isoniazid [with pyridoxine] and rifampicin, or 6 months of isoniazid [with pyridoxine]) aim to complete 2 months of

treatment before commencing biologic therapy. (Strong recommendation *for* the use of an intervention)

Recommendation 45. Any symptoms or signs suggestive of TB, or new exposure to TB or prolonged residence in a high-incidence setting, should prompt further clinical assessment and investigation, including a repeat interferon-γ release assay. Be aware that active TB on TNF antagonist therapy is often disseminated and extrapulmonary; symptoms may include unexplained weight loss, night sweats, nonresolving cough, haemoptysis and lymphadenopathy. (Strong recommendation *for* the use of an intervention)

Recommendation 46. Inform people that they should seek medical advice if symptoms of TB develop during or after treatment with a biologic therapy and issue a patient alert card in line with the Medicines and Healthcare Products Regulatory Agency (MHRA) guidance . (Strong recommendation *for* the use of an intervention)

Biologics and Vaccination

Recommendation 47. Do not give live vaccines to people on biologic therapy or to infants (up to 6 months of age) whose mothers have received biologic therapy beyond 16 weeks' gestation. (Strong recommendation *against* the use of an intervention)

Recommendation 48. Stop biologic therapy for at least 6 months before giving live vaccines, and for 12 months in the case of shingles (herpes zoster) vaccine. In general, biologic therapy can be started 4 weeks after administration of a live vaccine. Refer to the drug-specific SPC and Green Book (immunisation against infectious disease) for further information. (Strong recommendation *for* the use of an intervention)

Recommendation 49. Provide people on biologic therapy information on safe use of vaccinations, including which vaccination should be used and which to avoid (see BAD Patient Information Leaflet on immunization, www.bad.org.uk/leaflets , and the Green Book with reference to the clinical risk category 'immunosuppression'). (Strong recommendation *for* the use of an intervention)

Recommendation 50. Where possible, complete all required vaccinations prior to initiation of biologic therapy and review vaccination requirements during therapy with reference to the Green Book and the clinical risk category 'immunosuppression'. (Strong recommendation *for* the use of an intervention)

Important Contraindications to Biologic Therapies

Recommendation 51. Do not use TNF antagonists in people with demyelinating diseases and review alternative interventions in people who have an affected first-degree relative with demyelinating disease. (GPP)

Recommendation 52. Stop treatment and seek specialist advice if neurological symptoms suggestive of demyelinating disease develop during TNF antagonist therapy. Symptoms include loss or reduction of vision in one eye with painful eye movements; double vision; ascending sensory disturbance and/or weakness; problems with balance, unsteadiness or clumsiness; and altered sensation travelling down the back and sometimes into the limbs when bending the neck forwards (Lhermitte symptom); see the National Guideline Clearinghouse [NGC] summary of the NICE guideline on Multiple sclerosis: management of multiple sclerosis in primary and secondary care. (GPP)

Recommendation 53. Avoid TNF antagonist therapy in people with severe cardiac failure (New York Health Association [NYHA] class III and IV). (GPP)

Recommendation 54. Assess people with well-compensated (NYHA class I and II) cardiac failure (see the NICE interactive flowchart for diagnosing and assessing chronic heart failure) and consult with a cardiology specialist before using TNF antagonist therapy. (GPP)

Recommendation 55. Stop TNF antagonist therapy in the event of new or worsening pre-existing heart

failure and seek specialist advice. (GPP)

Recommendation 56. Exercise caution and consult a gastroenterology specialist before using secukinumab or ixekizumab in people with inflammatory bowel disease. (GPP)

Recommendation 57. In people undergoing elective surgery balance the potential benefit of preventing postoperative infection by stopping biologic therapy against the risk of developing severe or unstable disease. Advise stopping biologic therapy 3–5 times the half-life of the drug in question (refer to Table S1 in the Implementation Toolkit [see the "Availability of Companion Documents" field]) or the length of the treatment cycle (whichever is longer) between the last dose of therapy and the planned surgery. Inform the surgical team that the patient may be at higher risk of infection postoperatively. Restart biologic therapy postoperatively if there is no evidence of infection and wound healing is satisfactory. (GPP)

Definitions

Strength of Recommendation Ratings

Strength	Wording	Definition
Strong recommendation *for* the use of an intervention	'Offer' (or similar, e.g., 'provide', 'advise', 'screen')	Benefits of the intervention outweigh the risks; most patients would choose the intervention, while only a small proportion would not; for clinicians, most of their patients would receive the intervention; for policymakers, it would be a useful performance indicator
Weak recommendation *for* the use of an intervention	'Consider'	Risks and benefits of the intervention are finely balanced; many patients would choose the intervention, but many would not; clinicians would need to consider the pros and cons for the patient in the context of the evidence; for policy makers it would be a poor performance indicator where variability in practice is expected
No recommendation		Insufficient evidence to support any recommendation
Strong recommendation *against* the use of an intervention	'Do not offer'	Risks of the intervention outweigh the benefits; most patients would *not* choose the intervention, while only a small proportion would; for clinicians, most of their patients would *not* receive the intervention

Clinical Algorithm(s)

A clinical algorithm titled "Pathway algorithm to guide choice of biologic therapy in adults with psoriasis" is available in the original guideline document.

Scope

Disease/Condition(s)

Psoriasis

Guideline Category

Evaluation

Management

Treatment

Clinical Specialty

Allergy and Immunology

Dermatology

Family Practice

Pediatrics

Rheumatology

Intended Users

Advanced Practice Nurses

Nurses

Patients

Physician Assistants

Physicians

Guideline Objective(s)

To provide evidence-based recommendations on the use of biologic therapies (adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab) in adults, children and young people for the treatment of psoriasis

Target Population

Children and adults with all types of psoriasis

Interventions and Practices Considered

1. Use of biologic therapy
    - Criteria for eligibility
    - Prescribing biologic therapy, including discussion of benefits and risks with patient
    - Reviewing biologic therapy, including initial and ongoing assessment
    - Management of treatment failure (consideration of nonbiologic therapeutic approaches, e.g., inpatient topical therapy or standard systematic therapy)
2. Choice of biologic therapy
    - Consideration of psoriasis factors and patient factors
    - First-line therapy: ustekinumab, adalimumab, secukinumab
    - Second-line therapy: any currently available biologic (adalimumab, etanercept, ixekizumab, secukinumab, ustekinumab)
    - Infliximab only for very severe disease or when other agents have failed
    - Choice in children and young people: adalimumab, etanercept, ustekinumab
3. Transitioning to or between biologic therapies
4. Use of biologic therapy in special circumstances, including screening for viral infections
    - Pregnancy and conception
    - Viral infection (hepatitis B, hepatitis C, human immunodeficiency virus [HIV])
    - Risk of cancer or past history of cancer
5. Vaccination in people taking biologics

Major Outcomes Considered

- Clinical effectiveness
- Adverse effects and toxicity of drug therapy
- Drug withdrawal
- Physical, psychological, and social functioning
- Maternal and obstetric outcomes
- Serious infection, cancer, and tuberculosis (TB) rates
- Outcomes of previous treatments
- Disease flare or relapse

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): See the "Availability of Companion Documents" field for the full version of this guidance and related appendices.

Clinical Literature Search

Systematic literature searches were undertaken to identify the published clinical evidence relevant to the review questions. Searches were undertaken according to the parameters stipulated within the protocols. Databases were searched using relevant medical subject headings, free-text terms and study-type filters where appropriate. Where possible, searches were restricted to articles published in English. Studies published in languages other than English were not reviewed. All searches were conducted in PubMed, MEDLINE, EMBASE and Cochrane databases to identify key articles relevant to the questions. All searches for this draft version were completed between August and November 2015 depending on the review question and updated between August and October 2016 to ensure recommendations remain current to the best available evidence; search terms and strategies are detailed in Appendix B in the full version of the guideline.

Identifying and Appraising Evidence of Effectiveness

The technical team identified potentially relevant studies for the review question from the search results by reviewing the titles. Two members of the guideline development group (GDG) then reviewed the abstracts of these studies using the study protocol inclusion and exclusion criteria. Full papers were then obtained for those they were agreed as potentially relevant. The full papers were then reviewed against pre-specified inclusion/exclusion criteria to identify studies that addressed the review question. The studies were critically appraised using the appropriate study design checklists as specified in *Developing NICE guidelines: the manual* (2014).

Inclusion and Exclusion Criteria

The inclusion and exclusion of studies was based on the criteria defined in the review protocols, which can be found in Appendix C in the full version of the guideline. Excluded studies by review question (with the reasons for their exclusion) are listed in Appendix D in the full version of the guideline. The GDG was consulted about any uncertainty regarding inclusion or exclusion.

Type of Studies

See relevant review study protocols in the full version of the guideline.

Number of Source Documents

Refer to Appendix H in the full version of the guideline (see the "Availability of Companion Documents" field) for study selection flow charts and number of studies included in the quantitative synthesis.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Overall Quality of Outcome Evidence in Grading of Recommendations Assessment, Development and Evaluation (GRADE)

Level	Description
High	Further research is very unlikely to change our confidence in the estimate of effect
Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect and at change the estimate
Low	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very Low	Any estimate of effect is very uncertain

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): See the "Availability of Companion Documents" field for the full version of this guidance and related appendices.

Type of Analysis

Relevant data was extracted from the studies using RevMan5 software. Where relevant data was incomplete, e.g., standard deviation not provided for the mean change (from baseline) in Dermatology Life Quality Index (DLQI) values, the appropriate pharmaceutical company was contacted. Fixed-effects (Mantel-Haenszel) techniques (using an inverse variance method for pooling) were used to calculate the risk ratios (relative risk). The absolute risk difference was also calculated using GRADEpro software, using the event rate in the control arm of the results.

Where possible, meta-analyses and network meta-analyses were conducted to combine the data given in all studies for each of the outcomes of interest for the review question.

For some questions, the guideline development group (GDG) specified that data should be stratified, meaning that studies that varied on a particular factor were not combined and analysed together. Where stratification was used, this is documented in the individual question protocols (see Appendix C in the full version of the guideline).

Appraising the Quality of the Evidence by Outcomes

The evidence for outcomes from the included randomized controlled trials (RCTs) was evaluated and presented using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group (www.gradeworkinggroup.org/). The software (GRADEpro) developed by the GRADE working group was used to assess the quality of each outcome, taking into account individual study quality and the meta-analysis results.

Each outcome was first examined for each of the quality elements listed and defined in Table 2 in the full version of the guideline.

Details of how the 4 main quality elements (risk of bias, indirectness, inconsistency and imprecision) were appraised for each outcome are given in Sections 3.2.6.1 to 3.2.6.4 of the full version of the guideline. Publication or other bias was only taken into consideration in the quality assessment if it was apparent.

Grading the Quality of Clinical Evidence

Once an outcome had been appraised for the main quality elements, as above, an overall quality grade was calculated for that outcome. The scores from each of the main quality elements (0, -1 or -2) were summed to give a score that could be anything from 0 (the best possible) to -8 (the worst possible). However, scores were capped at -3. This final score was then applied to the starting grade that had originally been applied to the outcome by default, based on study design. For example, all RCTs started as HIGH and the overall quality became MODERATE, LOW or VERY LOW if the overall score was -1, -2 or -3 points respectively. The significance of these overall ratings is explained in Table 4. The reasons or criteria used for downgrading were specified in the footnotes of the GRADE tables.

On the other hand, observational interventional studies started at LOW, and so a score of -1 would be enough to take the grade to the lowest level of VERY LOW. Observational studies could, however, be upgraded if there was: a large magnitude of effect, a dose-response gradient, and if all plausible confounding would reduce a demonstrated effect.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Note from the National Guideline Clearinghouse (NGC): See the "Availability of Companion Documents" field for the full version of this guidance and related appendices.

This guideline has been developed using the British Association of Dermatologists (BAD) recommended methodology with reference to the Appraisal of Guidelines Research and Evaluation (AGREE II) instrument (www.agreetrust.org) and the Grading of Recommendations Assessment, Development and Evaluation (GRADE). Recommendations were developed for implementation in the National Health Service (NHS) (U.K.). Some safety aspects relating to screening, monitoring and contraindications to biologic therapy have not been covered by the review questions in this version. To address this gap relevant recommendations from the 2009 BAD guidelines were reviewed and updated with reference to the specific SPC and high quality, up-to-date guidelines and the Department of Health (DoH) Green Book (see section 11 in the full version of the guideline).

Developing the Review Questions and Outcomes

The guideline development group (GDG) agreed clinical questions relevant to the scope of the guideline and a set of outcome measures of importance to patients, ranked according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology.

Review questions were developed using a Population, Intervention, Comparison, Outcome (PICO) framework for intervention reviews.

This use of a framework guided the literature searching process, critical appraisal and synthesis of evidence, and facilitated the development of recommendations by the GDG. The review questions were drafted by the technical team and refined and validated by the GDG. The questions were based on the key clinical areas identified in the scope.

A total of six review questions were identified (see Table 1 in the full version of the guideline.

Full literature searches, critical appraisals and evidence reviews were completed for all the specified review questions.

Developing Recommendations

Over the course of the guideline development process, the GDG was presented with:

- Evidence tables of the reviewed literature. All evidence tables are in Appendix E (see the full version of the guideline).
- Summaries of the clinical evidence and quality.
- Forest plots (see Appendix F in the full version of the guideline).

Recommendations were drafted on the basis of the GDG's interpretation of the available evidence, taking into account the balance of benefits, harms and costs between different courses of action. The clinical benefit over harm (clinical effectiveness) was considered, focusing on the critical outcomes. The GDG took into account the clinical benefits and harms when one intervention was compared with another. The assessment of net clinical benefit was moderated by the importance placed on the outcomes (the GDG's values and preferences), and the confidence the GDG had in the evidence (evidence quality). The GDG assessed whether the net clinical benefit justified any differences in costs between the alternative interventions.

When clinical evidence was of poor quality, conflicting or absent, the GDG drafted recommendations based on its expert opinion. The considerations for making consensus-based recommendations include the balance between potential harms and benefits, practical and economic considerations, current practices, recommendations made in other relevant guidelines, patient preferences and equality issues. The consensus recommendations were agreed through discussions in the GDG. The GDG also considered whether the uncertainty was sufficient to justify delaying making a recommendation to await further research, taking into account the potential harm of failing to make a clear recommendation.

The GDG considered the appropriate 'strength' of each recommendation. This takes into account the quality of the evidence but is conceptually different. Some recommendations are 'strong' in that the GDG believes that the vast majority of healthcare and other professionals and patients would choose a particular intervention if they considered the evidence in the same way that the GDG has. This is generally the case if the benefits clearly outweigh the harms for most people (see Figure 2a in the full version of the guideline) and the intervention is likely to be cost effective. However, there is often a closer balance between benefits and harms (see Figure 2b in the full version of the guideline), and some patients would not choose an intervention whereas others would. This may happen, for example, if some patients are particularly averse to some side effect and others are not. For clinicians, this indicates the need to consider the pros/cons for the patient in context of the evidence and that variation in practice is expected. In these circumstances the recommendation is generally weaker although it may be possible to make stronger recommendations about specific groups of patients.

The GDG focused on the following factors in agreeing the wording of the recommendations:

- The actions health professionals need to take.
- The information readers need to know.
- The strength of the recommendation (for example the words 'offer', 'assess', 'advise', 'discuss', etc. were used for strong recommendations and 'consider' for weaker recommendations).

The involvement of patients (and their carers if needed) in decisions on treatment and care.

The main considerations specific to each recommendation are outlined in the 'Link from evidence to recommendations' sections within each chapter in the full guideline document.

Rating Scheme for the Strength of the Recommendations

Strength of Recommendation Ratings

Strength	Wording	Definition
Strong recommendation *for* the use of an intervention	'Offer' (or similar, e.g., 'provide', 'advise', 'screen')	Benefits of the intervention outweigh the risks; most patients would choose the intervention, while only a small proportion would not; for clinicians, most of their patients would receive the intervention; for policymakers, it would be a useful performance indicator
Weak recommendation *for* the use of an intervention	'Consider'	Risks and benefits of the intervention are finely balanced; many patients would choose the intervention, but many would not; clinicians would need to consider the pros and cons for the patient in the context of the evidence; for policy makers it would be a poor performance indicator where variability in practice is expected
No recommendation		Insufficient evidence to support any recommendation
Strong recommendation *against* the use of an intervention	'Do not offer'	Risks of the intervention outweigh the benefits; most patients would *not* choose the intervention, while only a small proportion would; for clinicians, most of their patients would *not* receive the intervention

Cost Analysis

Cross reference was made to any relevant National Institute for Health and Care Excellence (NICE) guidance and associated health economic evaluation. Drug acquisition costs, resource use and practical considerations were also considered, based on the experience of the guideline development group (GDG) were also considered. Formal health economic analyses were not performed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Validation Process

The draft document was made available for a 1-month consultation to all relevant stakeholders including health care professionals, patient support groups and members of the pharmaceutical industry (see Appendix G in the full version of the guideline) (see the "Availability of Companion Documents" field). All comments were reviewed by the guideline development group (GDG) and recommendations revised if appropriate (for example, in light of important new evidence or other considerations not previously considered by the GDG). Following further review, the finalized version was peer-reviewed by the Clinical Standards Unit of the British Association of Dermatology (BAD) (which includes the Therapy & Guidelines sub-committee) prior to publication.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of biologic therapies in adults, children, and young people for the treatment of psoriasis

Refer to the "Trade-off between benefits and harms" sections of the full version of the guideline (see the "Availability of Companion Documents" field) for details about benefits of specific interventions.

Potential Harms

- Adverse effects associated with biologic therapies are available in the summaries of product characteristics (SPCs). The U.K. version can be accessed at www.medicines.org.uk/emc .
- Tumour necrosis factor (TNF) antagonist therapy has been associated with the development of, or worsening of, demyelinating disease. The drug specific SPC for all three TNF antagonists advise caution in patients with pre-existing or new onset disease.
- Exercise caution and consult a gastroenterology specialist before using secukinumab or ixekizumab in people with inflammatory bowel disease.

Refer to the "Trade-off between benefits and harms" sections of the full version of the guideline (see the "Availability of Companion Documents" field) for details about potential harms of specific interventions.

Contraindications

Contraindications

- Live vaccinations can cause severe or fatal infections in immunosuppressed individuals due to the extensive replication of the vaccine strain and therefore are contraindicated in patients on biologic therapy and in infants (up to 6 months of age) whose mothers have received biologic therapy beyond 16 weeks gestation.
- Whilst there remains a lack of evidence that tumour necrosis factor (TNF)-antagonists lead to adverse outcomes in people with concomitant heart failure when they are used to treat chronic inflammatory disorders, the drug specific summary of product characteristics (SPC) for all three TNF antagonists state that they are contraindicated in patients with moderate or severe heart failure and should be used with caution in mild heart failure.

Refer to the "Major Recommendations" field for important contraindications to biologic therapies.

Qualifying Statements

Qualifying Statements

- The recommendations were developed for implementation in the National Health Service (NHS) in the United Kingdom (U.K.). Note that the guideline recommendations will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline assumes that prescribers cross-reference a drug's SPC to inform clinical decision making for individual patients. Where relevant, this guidance applies to biosimilars (similar biological medical products), subject to recommendations given within the British Association of Dermatologists (BAD) position statement and the European Medicines Agency guidelines. This guidance does not cover agents licensed outside the U.K. or use of biologic therapies for indications other than psoriasis or use when psoriatic arthritis is the main indication.
- This guideline has been prepared on behalf of the BAD and is based on the best data available when the document was prepared. It is recognized that under certain conditions it may be necessary to deviate from the guidelines and that the results of future studies may require some of the recommendations herein to be changed. Failure to adhere to these guidelines should not necessarily be considered negligent, nor should adherence to these recommendations constitute a defence against a claim of negligence. Limiting the review to English-language references was a pragmatic decision, but the authors recognize this may exclude some important information published in other languages.
- Use of biologic therapy where psoriatic arthritis is the main indication is outside the scope of this guideline and so a formal evidence review on the safety and efficacy of biologic therapy for psoriatic arthritis was not carried out.
- The views expressed in this guidance are those of the authors and not necessarily those of the National Health Service, the National Institute for Health Research (NIHR) or the Department of Health.

Implementation of the Guideline

Description of Implementation Strategy

Implementation Toolkit

To support implementation of the recommendations, a number of documents have been developed (see the Implementation Toolkit [see the "Availability of Companion Documents" field]). These comprise a summary of licensed indications and posology for biologic therapy (Table S1); a decision aid, informed by the evidence reviews, to help patients and clinicians choose the appropriate biologic therapy (Table S2); a suggested schedule for screening and monitoring (Table S3) and a list of groups at increased risk of tuberculosis (TB), hepatitis B, hepatitis C and HIV (Table S4).

Implementation Tools

Audit Criteria/Indicators

Chart Documentation/Checklists/Forms

Clinical Algorithm

Patient Resources

Tool Kits

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Smith CH, Jabbar-Lopez ZK, Yiu ZZ, Bale T, Burden AD, Coates LC, Cruickshank M, Hadoke T, MacMahon E, Murphy R, Nelson-Piercy C, Owen CM, Parslew R, Peleva E, Pottinger E, Samarasekera EJ, Stoddart J, Strudwicke C, Venning VA, Warren RB, Exton LS, Mohd Mustapa MF. British Association of Dermatologists guidelines for biologic therapy for psoriasis 2017. Br J Dermatol. 2017 Sep;177(3):628-36. [17 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

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Guideline Developer(s)

British Association of Dermatologists - Medical Specialty Society

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Guideline Committee

British Association of Dermatologists (BAD) Clinical Standards Unit, Therapy & Guidelines Subcommittee

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Financial Disclosures/Conflicts of Interest

Conflicts of Interest

Details of declarations of interests (cumulative, throughout the project) can be found in the full version of the guideline (Appendix A in File S2 [see the "Availability of Companion Documents" field]) and are consistent with the National Institute of Health and Care Excellence (NICE) Accreditation policy.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Smith CH, Anstey AV, Barker JN, Burden AD, Chalmers RJ, Chandler DA, Finlay AY, Griffiths CE, Jackson K, McHugh NJ, McKenna KE, Reynolds NJ, Ormerod AD. British Association of Dermatologists' guidelines for biologic interventions for psoriasis 2009. Br J Dermatol. 2009 Nov;161(5):987-1019. [226 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the British Journal of Dermatology (BJD) Web site and British Association of Dermatologists (BAD) Web site.

Availability of Companion Documents

The following are available from the British Journal of Dermatology (BJD) Web site and British Association of Dermatologists (BAD) Web site:

Guidelines for biologic therapy for psoriasis. Full guideline. London (UK): British Association of Dermatologists (BAD); 2017 Apr. 395 p.

British Association of Dermatologists guidelines for biologic therapy for psoriasis 2017. Implementation toolkit. London (UK): British Association of Dermatologists (BAD); 2017. 10 p.

British Association of Dermatologists guidelines for biologic therapy for psoriasis 2017. Audit standards. London (UK): British Association of Dermatologists (BAD); 2017 Apr. 3 p.

The Psoriasis Area and Severity Index (PASI), Dermatology Life Quality Index (DLQI) and Psoriasis Epidemiology Screening Tool (PEST) are available from the BAD Web site.

Patient Resources

The following are available:

Psoriasis: an overview. Patient information leaflet. London (UK): British Association of Dermatologists; 2015 Sep. 6 p. Available from the British Association of Dermatologists (BAD) Web site.

Etanercept. Patient information leaflet. London (UK): British Association of Dermatologists; 2016 Sep. 6 p. Available from the BAD Web site.

Infliximab. Patient information leaflet. London (UK): British Association of Dermatologists; 2016 Apr. 6 p. Available from the BAD Web site.

Adalimumab. Patient information leaflet. London (UK): British Association of Dermatologists; 2015 Jun. 6 p. Available from the BAD Web site.

Ustekinumab. Patient information leaflet. London (UK): British Association of Dermatologists; 2016 Feb. 6 p. Available from the BAD Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on May 11, 2007. The information was verified by the guideline developer on June 13, 2007. This summary was updated by ECRI Institute on May 15, 2008 following the U.S. Food and Drug Administration advisory on Enbrel (etanercept). This summary was updated by ECRI Institute on October 30, 2008 following the U.S. Food and Drug Administration advisory on Raptiva (efalizumab). This summary was updated by ECRI Institute on April 14, 2009 following the U.S. Food and Drug Administration advisory (voluntary withdrawal) of Raptiva (efalizumab). This summary was updated by ECRI Institute on August 20, 2009, following the U.S. Food and Drug Administration advisory on Tumor Necrosis Factor (TNF) blockers. This summary was updated by ECRI Institute on September 10, 2010. The updated information was verified by the guideline developer on November 9, 2010. This summary was updated by ECRI Institute on October 12, 2011 following the U.S. Food and Drug Administration (FDA) advisory on Tumor Necrosis Factor-alpha (TNFα) Blockers. This summary was updated by ECRI Institute on December 5, 2017. The updated information was verified by the guideline developer on December 19, 2017.

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